

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL 1456

Master File No. 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENTS RELATES TO:
State of Montana v. Abbott Labs., Inc., et al.,
No. CV-02-09-H-DWM

**IMMUNEX CORPORATION'S ANSWER TO
STATE OF MONTANA'S SECOND AMENDED COMPLAINT**

Defendant Immunex Corporation ("Immunex") answers the Second Amended Complaint ("SAC"), dated as of August 1, 2003, as follows:

The SAC improperly and repetitively refers to Immunex and other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against Immunex.

Immunex was acquired by defendant Amgen during this litigation but remains separately incorporated. Immunex is not responsible for the actions of Amgen, and Amgen is not responsible for the actions of Immunex. Amgen has assumed the marketing of Enbrel, and it will answer as to Enbrel and all related activities.

Intentionally ambiguous pleading is improper and insufficient to apprise Immunex in any meaningful sense of the allegations asserted against it. Immunex has nevertheless attempted to respond to the State's allegations to the extent possible under the

circumstances. To the extent allegations refer to the knowledge, conduct, or actions of other defendants or entities, Immunex is without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, Immunex denies those allegations. Immunex answers the State's allegations on behalf of itself only, even when the State's allegations refer to alleged conduct by Immunex and other persons or entities. The SAC improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the allegations of the SAC are vague or conclusory. The SAC also includes terms that are undefined and susceptible to different meanings. By addressing factual allegations and not pointing out each and every ambiguity or challenging every innuendo or conclusion, Immunex does not admit any of the State's interpretations or conclusions. To save space, Immunex will not repeat the above and similar caveats each time they apply.

The SAC contains purported quotations from a number of sources, many of which are unidentified. Referencing or purporting to summarize a potential item of evidence is not an allegation and does not require an answer. In responding to allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote was or was not true at the time the document was created, much less before or after its creation, or that the material is relevant or admissible in this action.

Immunex denies each and every allegation contained in the SAC, except as specifically admitted, and any factual allegation admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendo, or speculation contained in or suggested by any allegation or the SAC as a whole. Moreover, Immunex

specifically denies any allegations contained in headings, footnotes, the Table of Contents, and unnumbered paragraphs in the SAC.

References to "the State" and similar references include not only the State of Montana but each person or entity on whose behalf plaintiff seeks, directly or indirectly, to pursue this action.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer. Immunex numbers its answering paragraphs below to reflect the relevant paragraph or paragraphs in the SAC.

1. Immunex admits that the State purports to bring this alleged action against Immunex and other pharmaceutical companies but otherwise denies each other or different allegation of Paragraph 1. Immunex denies that the State is entitled to maintain this action in the manner alleged. Immunex further denies the existence of, and its participation in, any "AWP scheme."

2. Immunex admits that it has manufactured or distributed certain medicines in Montana as alleged in Paragraph 2. Immunex admits that payors for prescription pharmaceuticals include federal and/or state governments, private insurers and self-insured employers, and private individuals. Except as specifically admitted and to the extent that any remaining allegations are directed at Immunex and require a response, Immunex denies those allegations.

3. Paragraph 3 contains no allegations against Immunex and therefore require no answer from Immunex.

4. Immunex admits that it spent money to develop and market drugs. Immunex denies the existence of, or its participation in, any "profit incentive" scheme as alleged in Paragraph 4. Except as specifically admitted and to the extent that any remaining

allegations are directed at Immunex and require a response, Immunex denies those allegations.

5 – 6. Immunex admits that certain medicines are covered under Medicare Part B, and that during certain times Congress mandated that Medicare Part B reimbursement be based upon AWP, an industry practice and term of art incorporated by the government as a reimbursement benchmark, and that Medicare Part B medicines are generally administered in a healthcare provider's office. Immunex admits that it reports some pricing information for its medicines to independent pharmaceutical industry publications. Immunex admits that AWP benchmarks published in trade publications can be higher than the prices ultimately paid by providers. Immunex denies the existence of, and its participation in, any "AWP scheme" or "unlawful agreement" as alleged in Paragraph 6. Except as specifically admitted and to the extent that any remaining allegations are directed at Immunex, Immunex denies those allegations in Paragraphs 5 – 6.

7. Immunex denies the existence of, and its participation in, any "AWP scheme" or "AWP Inflation Scheme" as alleged in Paragraph 7. Immunex denies that it "fraudulently reports" its drugs on a "fictitious and fraudulent AWP." To the extent that the remaining allegations in Paragraph 7 are directed at Immunex, Immunex denies those allegations.

8. Immunex admits that certain medicines are covered under Medicare Part B, and that during certain times Congress mandated that Medicare Part B reimbursement be based upon AWP, an industry practice and term of art incorporated by the government as a reimbursement benchmark, and that Medicare Part B medicines are generally administered in a healthcare provider's office. Immunex admits that AWP benchmarks published in trade publications can be higher than the prices ultimately paid by providers. Immunex denies that it has engaged "secret profits" or "inflated AWP schemes" as alleged in Paragraph 8.

Except as specifically admitted and to the extent that any remaining allegations are directed at Immunex, Immunex denies those allegations.

9. To the extent the allegations in Paragraph 9 are directed at and require a response from Immunex, Immunex denies those allegations.

10. Immunex denies the existence of, and its participation in, any "perversion of the type of competitive behavior" as alleged in Paragraph 10, and denies any remaining allegation.

11 – 12. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, a response is not required for Paragraph 11 – 12. To the extent a response is required, Immunex denies the allegations in Paragraphs 11 – 12.

13. Immunex denies the allegations in Paragraph 13.

14-17. Immunex denies the existence of, and its participation in, any "AWP Inflation Scheme" or "illegal AWP Scheme" as alleged in Paragraphs 15 – 17. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, a response is not required for certain allegations in Paragraph 15. Except as specifically admitted and to the extent that any remaining allegations in Paragraphs 14 – 17 are directed at and require a response from Immunex, Immunex denies those allegations.

18. Immunex admits that the State purports to bring this action as alleged in Paragraph 18, but Immunex denies that the State is entitled to maintain this action in the manner alleged. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 18 are directed at Immunex, Immunex denies those allegations.

19 – 20. Immunex denies the existence of, and its participation in, any "AWP Inflation Scheme" as alleged in Paragraphs 19 – 20 and denies any remaining allegations.

21 – 23. Immunex admits that the State purports to bring this action as alleged in Paragraphs 21 – 23, but Immunex denies that the State is entitled to maintain this action in the manner alleged. Except as specifically admitted and to the extent that the remaining allegations in Paragraphs 21 – 23 are directed at Immunex, Immunex denies those allegations.

24 - 28. Immunex admits that the State purports to bring this action, and that the State seeks relief as alleged in Paragraphs 24 – 28. Immunex denies that this action can be maintained in the manner alleged, and further denies that the State is entitled to relief under Counts I through V. Except as specifically admitted and to the extent that the remaining allegations in Paragraphs 24 – 28 are directed at Immunex and require a response, Immunex denies those allegations.

29. Immunex denies the allegations in Paragraph 29.

30. Immunex admits that its products have been sold in the State of Montana. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 30 are directed at Immunex and require a response, Immunex denies those allegations.

31 – 79. The allegations in Paragraphs 31 – 79 are directed to other defendants and contain no allegations against Immunex and therefore require no answer from Immunex.

80. Immunex admits that it became a wholly-owned subsidiary of Amgen, Inc., during the pendency of this litigation and that its principal place of business as of the commencement of the action is Seattle, Washington. Immunex admits that it developed products for the treatment of cancer, asthma, rheumatoid arthritis, inflammatory diseases, infectious diseases, and cardiovascular diseases. Immunex's Annual Reports speak for themselves. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 80.

81. Immunex admits that it was acquired by Amgen in July 2002. Immunex denies any and all remaining allegations in Paragraph 81.

82. Immunex admits that it manufactured and distributed several pharmaceuticals that were administered by Medicare Plan B providers in most if not all states. Immunex denies any and all remaining allegations in Paragraph 82.

83 – 111. The allegations in Paragraphs 83 – 111 are directed to other defendants and contain no allegations against Immunex and therefore require no answer from Immunex.

112. Paragraph 112 contains no allegations against Immunex and therefore require no answer from Immunex.

113 – 121. Immunex states that the Chartbook, Chartbook Update, and Fact Sheet cited in Paragraphs 113 – 121 are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the Chartbook, Chartbook Update, or Fact Sheet or that such are applicable to Immunex. Immunex further alleges that it is without information sufficient to form a belief concerning the accuracy of the allegations of Paragraph 113 – 121 and therefore denies those allegations.

122. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations of Paragraph 122 and therefore denies those allegations.

123. Immunex denies the allegations of Paragraph 123.

124. Paragraph 124 contains no allegations against Immunex and therefore require no answer from Immunex. To the extent a response is required, Immunex denies the allegations in Paragraph 124.

125 – 128. Paragraphs 125 - 128 contain no allegations against Immunex and therefore require no answer from Immunex.

129. Immunex admits that it distributed pharmaceuticals through wholesalers, retailers, hospitals, providers, and managed care organizations. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 129 are directed at Immunex and require a response, Immunex denies those allegations.

130. Immunex states that the Chartbook cited in Paragraph 130 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the Chartbook or that such is applicable to Immunex. Immunex further alleges that it is without information sufficient to form a belief concerning the accuracy of the remaining allegations of Paragraph 130 and therefore denies those allegations.

131 & 134. Immunex admits that "WAC" is an acronym for "wholesale acquisition cost" and that "DP" is an acronym for "direct price." Except as specifically admitted and to the extent that the remaining allegations in Paragraphs 131 and 134 are directed at Immunex and require a response, Immunex denies those allegations.

132. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 132 are directed at Immunex and require a response, Immunex denies those allegations.

133 & 139. Immunex states that the Chartbook cited in Paragraphs 133 and 139 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the Chartbook or that such is applicable to Immunex. Immunex further alleges that it is without information sufficient to form a belief concerning the accuracy of the remaining allegations of Paragraphs 133 and 139 and therefore denies those allegations.

135. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraph 135 and therefore denies those allegations.

136 – 138. Paragraphs 136 – 138 contain no allegations against Immunex and therefore require no answer from Immunex. To the extent that Paragraphs 136 – 138 require a response from Immunex, Immunex alleges that it is without information sufficient to form a belief concerning the accuracy of the remaining allegations of Paragraphs 136 – 138 and therefore denies those allegations.

140. Immunex admits that DP generally is the price referenced when there are no applicable discounts. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 140 are directed at Immunex and require a response, Immunex denies those allegations.

141. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 141 are directed at Immunex and require a response, Immunex denies those allegations.

142 – 143. Immunex admits the allegations in Paragraphs 142 – 143.

144 – 145. Paragraphs 144 – 145 contain no allegations against Immunex and therefore require no answer from Immunex.

146. Immunex admits that 42 C.F.R. § 405.517 set forth the reimbursement methodology for drugs covered by Medicare Part B and is the best evidence of its contents. Immunex is without information sufficient to form a belief concerning the accuracy of the remaining allegations of Paragraph 146 and therefore denies those allegations.

147 – 148. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex denies the allegations in the first sentence of

Paragraph 147 insofar as it contains material in quotation marks the source of which is not identified. Immunex admits that 42 C.F.R. § 405.517 was amended on January 1, 1998, to "provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP." Immunex denies any and all remaining allegations in Paragraphs 147 – 148 that pertain to it.

149 – 150. Immunex admits that the Medicare Program had publicly announced its use of the AWP as a reimbursement benchmark. Immunex states that Program Memo AB-99-63 cited in Paragraphs 149 – 150 is the best evidence of its contents. Immunex denies any and all remaining allegations in Paragraphs 149 – 150 that pertain to it.

151. Immunex admits that there are no regulations that describe how AWP's are to be calculated or a regulatory process specifically designated for approving AWP's. Immunex admits that there are several independently produced pharmaceutical industry compendia that periodically publish AWP and other reimbursement benchmarks and prices. Immunex also admits that it reports certain pricing information for its medicines to independent pharmaceutical industry publications. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 151 that pertain to it.

152 – 153. Paragraphs 152 – 153 contain no allegations against Immunex and therefore require no answer from Immunex.

154 - 157. Immunex states that the Reports cited in Paragraphs 154 – 157 are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the reports or that such are applicable to Immunex. Immunex further alleges that it is without information sufficient to form a belief concerning the accuracy of the remaining allegations in Paragraphs 154 – 157 and therefore denies those allegations.

158. Paragraph 158 contains no allegations against Immunex and therefore requires no answer from Immunex.

159. Immunex admits that 42 C.F.R. § 440.120 defines prescription drugs and is the best evidence of its content. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 159 that pertain to it.

160 – 161. Immunex states that the Report cited in Paragraphs 160 – 161 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the reports or that such are applicable to Immunex. Immunex further alleges that it is without information sufficient to form a belief concerning the accuracy of the remaining allegations in Paragraphs 160 – 161 and therefore denies those allegations.

162. Immunex admits that Mont. Admin. R. 37.86.1105 and 1101(1) and (3), and 42 C.F.R. § 447.331-32 are the best evidence of their contents. Immunex states that the Program cited in Paragraph 162 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the reports or that such are applicable to Immunex. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 162 that pertain to it.

163. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraph 163 and therefore denies those allegations.

164. Paragraph 164 contains no allegations against Immunex and therefore require no answer from Immunex.

165. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraph 165 and therefore denies those allegations.

166. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex denies any and all remaining allegations in Paragraph 166 that pertain to it.

167. Immunex admits that there are several independently produced pharmaceutical industry compendia that periodically publish AWP and other reimbursement benchmarks and prices. Immunex denies any and all remaining allegations in Paragraph 167 that pertain to it.

168. Immunex admits that it reported certain pricing information for its medicines to independent pharmaceutical industry publications. Immunex denies any and all remaining allegations in Paragraph 168 that pertain to it.

169. Immunex denies the allegations in Paragraph 169.

170 – 171. The April 2003 OIG report cited in Paragraphs 170 – 171 is the best evidence of its contents, but Immunex does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to Immunex or are retroactive. Immunex denies any and all remaining allegations in Paragraphs 170 – 171 that pertain to it.

172. Immunex denies the allegations in Paragraph 172.

173 – 175. Immunex denies the existence of, and its participation in, any "AWP Inflation Scheme" as alleged in Paragraphs 173 – 175. To the extent that the remaining allegations in Paragraphs 173 – 175 are directed at Immunex and require a response, Immunex denies those allegations.

176. Immunex admits that it reported certain pricing information for its medicines to independent pharmaceutical industry publications. Immunex denies any and all remaining allegations in Paragraph 176 that pertain to it.

177. Immunex denies the allegations in Paragraph 177.

178 & 180. Immunex denies the existence of, and its participation in, any "scheme" as alleged in Paragraphs 178 and 180. To the extent that the remaining allegations in Paragraphs 178 and 180 are directed at Immunex and require a response, Immunex denies those allegations.

179. Immunex admits that it reported certain pricing information for its medicines to independent pharmaceutical industry publications. Immunex also admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex denies any and all remaining allegations in Paragraph 179 that pertain to it.

181 – 184. Immunex denies the allegations in Paragraphs 181 – 184.

185. Immunex denies the existence of, and its participation in, any "scheme" as alleged in Paragraph 185. To the extent that the remaining allegations in Paragraph 185 are directed at Immunex and require a response, Immunex denies those allegations.

186 – 187. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex also admits that 42 C.F.R. § 405.517 is the best evidence of its content. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraphs 186 – 187 that pertain to it.

188 – 189. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex also admits that 42 C.F.R. § 447.332(b) and Mont. Admin. R. 37.86.1101(3) are the best evidence of their content. Except as specifically

admitted, Immunex denies any and all remaining allegations in Paragraphs 188 - 189 that pertain to it.

190 – 191. Immunex denies the allegations of Paragraphs 190 – 191.

192. Immunex admits that the State purports to quote from an unidentified "industry consultant" as alleged in Paragraph 192, but Immunex denies any allegations suggested by the quoted material.

193. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Except as specifically admitted and to the extent that any remaining allegations are directed at Immunex and require a response, Immunex denies those allegations.

194. Paragraph 194 contains no allegations against Immunex and therefore requires no answer from Immunex. To the extent a response is required, Immunex denies the allegations in Paragraph 194 of the SAC.

195. Immunex denies the allegations in Paragraph 195.

196 – 200. Immunex states that the *Red Book* and the unidentified DOJ report cited in Paragraph 196 and the pleadings cited in Paragraphs 197 – 200, are the best evidence of their contents, but does not admit that the contents were accurate when created. To the extent the allegations in Paragraphs 196 – 200 are deemed to include allegations against Immunex, Immunex denies them.

201 – 209. Immunex denies the allegations in Paragraphs 201 – 209 that pertain to it.

210. Immunex admits that some governmental agencies have conducted investigations concerning pricing in the pharmaceutical industry. Immunex denies the remaining allegations in Paragraph 210 that pertain to it.

211 – 212. Immunex denies the existence of, and its participation in, any "scheme" cited in Paragraph 211. Immunex states that the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 211 – 212 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the findings, opinions, statements, or conclusions of Congressman Stark, or that such are applicable to Immunex.

213. Immunex admits that some governmental agencies have conducted investigations concerning pricing in the pharmaceutical industry. Immunex denies any and all remaining allegations in Paragraph 213 that pertain to it.

214 – 215. Immunex denies any allegations in Paragraphs 214 – 215 that pertain to it.

216 - 464 The allegations in Paragraphs 216 – 464 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 216 – 464 are deemed to include allegations against Immunex, Immunex denies them.

465 – 466. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraphs 465 – 466. Immunex denies that it has stated "fraudulent AWP." Immunex denies that the State is entitled to judgment or any relief and denies any other allegations in Paragraphs 465 – 466 that pertain to it.

467. Immunex admits that it reported certain pricing and reimbursement information for its medicines to independent pharmaceutical industry publications during the purported time period. Immunex admits that on occasion prior to July 1995 it reported suggested AWP's to independent pharmaceutical industry publications. Immunex states that the October 26, 2000, letter is the best evidence of its contents, but does not admit that the

contents were accurate when created. Immunex denies that the State has accurately characterized the letter. Immunex states that the interview cited in document IAWP003071 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the conclusions the State has drawn from the documents cited in Paragraph 467 are accurate and denies any and all remaining allegations in Paragraph 467.

468. Immunex states that the January 12, 1996, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex states that the January 12, 1995, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex admits that it reported certain pricing and reimbursement information for its medicines to independent pharmaceutical industry publications during the purported time period. Immunex admits that on occasion prior to July 1995 it reported suggested AWP's to independent pharmaceutical industry publications. Immunex denies any conclusions the State has drawn from the documents cited in Paragraph 468 and denies any and all remaining allegations in Paragraph 468.

469. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 469. Immunex denies any and all remaining allegations in Paragraph 469.

470. Immunex states the "internal document" cited in Paragraph 470 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the conclusions the State has drawn from the document cited in Paragraph 470 are accurate and denies any and all remaining allegations in Paragraph 470.

471 – 472. Immunex admits that it understood that AWP was a reimbursement benchmark. Immunex states that "internal documents" IAWP012961 and IAWP051149-52

are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions the State has drawn from the documents cited in Paragraphs 471 – 472 and denies any and all remaining allegations in Paragraphs 471 – 472.

473. Immunex states that the February 21, 1997, memo is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions the State has drawn from the documents cited in Paragraph 473 and denies any and all remaining allegations in Paragraph 473.

474. Immunex states that documents IAWP003407-13 and IAWP016686-88 are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions the State has drawn from the documents cited in Paragraph 474 and denies any and all remaining allegations in Paragraph 474.

475. Immunex admits that it produced documents pursuant to government requests. Immunex admits that the State has reviewed such documents and that each such document is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized such documents or that such conclusions the State has drawn are accurate and denies any and all remaining allegations in Paragraph 475.

476. Immunex states that document IAWP005418 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions the State has drawn from the document. Immunex denies all remaining allegations in Paragraph 476.

477. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 477. Immunex admits that the governmental agencies listed in

Paragraph 477 have conducted investigations concerning pricing in the pharmaceutical industry and that Immunex has received and responded to requests for information.

Immunex denies any and all remaining allegations in Paragraph 477.

478. Immunex admits that it distributed methotrexate sodium and leucovorin calcium in 1997 and that the AWP reimbursement benchmark for the drugs might have been higher than the actual prices paid by some customers of wholesalers. Immunex states that the DHHS Report cited in Paragraph 478 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the DHHS Report and denies any and all remaining allegations in Paragraph 478.

479. Immunex admits that it distributed Novantrone® in 1997 and that the AWP reimbursement benchmark for the drug was higher than the actual prices that might have been paid by some customers of wholesalers. Immunex states that the DHHS 1997 Report is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized the DHHS 1997 Report and denies any and all remaining allegations in Paragraph 479.

480. Immunex states that document IAWP016524 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions the State has drawn from the document cited in Paragraph 480 and denies any and all remaining allegations in Paragraph 480.

481 – 602. The allegations in Paragraphs 481 – 602 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 481 – 602 are deemed to include allegations against Immunex, Immunex denies them.

603 – 634. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, Immunex does not respond to the Best Price allegations contained in Paragraphs 603 – 634. To the extent a response is required and the allegations in Paragraphs 603 – 634 are deemed to include allegations against Immunex, Immunex denies them.

635. Immunex denies the allegations in Paragraph 635.

636. Immunex states that the 2003 CMS document cited in Paragraph 636 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the State has accurately characterized any alleged CMS finding, opinion, statement, or conclusion. Immunex admits that it sells its medicines in competitive markets and, as such, takes steps to keep certain information relating to its medicines confidential. Immunex denies any and all remaining allegations in Paragraph 636 that pertain to it.

637 – 640. Immunex denies any allegations in Paragraphs 637 – 640 that pertain to it.

641. In response to the allegations in Paragraph 641, Immunex denies that the State lacked inquiry or other notice of the issues associated with reliance on AWP as a reimbursement benchmark. Immunex specifically alleges, to the contrary, that such issues were well-known for more than a decade before the State elected to bring this suit and that the State's allegations in the suit estop it from denying that it was on inquiry or other notice.

642 – 643. The allegations in Paragraphs 642 – 643 state legal conclusions to which no response is required. Immunex denies any allegations in Paragraphs 642 – 643 that pertain to it.

644. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 644. Immunex denies any and all remaining allegations in Paragraph 644.

645. Paragraph 645 contains no allegations against Immunex and therefore requires no answer from Immunex.

646 – 648. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations in Paragraphs 646 – 648 and therefore denies those allegations.

649. Immunex admits that some Medicare beneficiaries obtain supplemental insurance. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 649.

650 – 653. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraphs 650 – 653. Immunex denies any and all remaining allegations in Paragraphs 650 – 653.

654. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 653 in answering Paragraph 654.

655. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 655. Immunex denies any and all remaining allegations in Paragraph 655.

656 – 660. Immunex denies the allegations in Paragraphs 656 – 660 that pertain to it. Immunex further denies that the State has suffered damages or injuries as alleged in Paragraphs 656 – 660.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count I.

661. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 660 in answering Paragraph 661.

662 – 667. Immunex denies the existence of, and its participation in, any "AWP Scheme" as alleged in Paragraph 662. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, Immunex does not respond to the Best Price allegations contained in Paragraphs 662 and 663. Immunex denies any remaining allegations in Paragraphs 662 – 667 and subparts that pertain to it. Immunex further denies that the State has suffered damages or injuries as alleged in Paragraphs 662 – 667.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count II.

668. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 667 in answering Paragraph 668.

669. Immunex admits that the State purports to bring this action as alleged in Paragraph 669, but Immunex denies that this State is entitled to maintain this action in the manner alleged. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 669 are directed at Immunex, Immunex denies those allegations.

670. Immunex admits that it was listed in the Montana Medicaid drug formulary. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 670.

671 – 675. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, a response is not required for Paragraphs 671 – 675.

676 – 679. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, Immunex does not respond to the Best Price allegations contained in Paragraph 679. Immunex denies the allegations in Paragraphs 676 – 679 and subparts that

pertain to it. Immunex further denies that the State has suffered damages or injuries as alleged in Paragraphs 676 – 679.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count III.

680. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 679 in answering Paragraph 680.

681. Immunex admits that the State purports to bring this action as alleged in Paragraph 681, but Immunex denies that this State is entitled to maintain this action in the manner alleged. Except as specifically admitted and to the extent that the remaining allegations in Paragraph 681 are directed at Immunex, Immunex denies those allegations.

682 – 687. Because the Court dismissed the Best Price claims in its Order dated June 10, 2004, a response is not required for Paragraphs 682 – 687 and subparts.

688 – 691. Immunex denies the allegations in Paragraphs 688 – 691 that pertain to it. Immunex further denies that the State has suffered damages or injuries as alleged in Paragraphs 688 – 691.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count IV.

692. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 691 in answering Paragraph 692.

693 – 694. Immunex denies the allegations in Paragraphs 693 – 694 and subparts.

Immunex denies the State is entitled to a judgment or any other relief requested in the Prayer for Relief for Count V.

DEFENSES

Without assuming any burden that it would not otherwise have, and without waiving any denial above, Immunex further responds to the SAC by alleging the following:

1. The Complaint fails to state a claim upon which relief may be granted.
2. Immunex has not acted in a manner that is illegal, oppressive, or fraudulent and in fact acted in good faith, with just cause, and in accordance with established industry practices and government requirements and policies.
3. The federal government adopted AWP as a reimbursement benchmark with knowledge that it was not a calculation of actual average prices and with no express or implicit definition contrary to industry practice. For public policy and other reasons, the federal government retained AWP as a reimbursement benchmark in the face of years of criticism that it was not a calculation of actual average prices. To the extent that the State has adopted the federal government's AWP term, the State is bound by defenses applicable to the federal government. Among the defenses that arise from those and other relevant circumstances are the following:
 - A. The State's claims are barred, in whole or in part, by the political question, separation of powers, and filed rate doctrines. The relief sought by the State would interfere with legislative decisions and functions.
 - B. The State's claims are barred, in whole or in part, because Immunex has complied with all applicable statutes and regulations.

- C. The State's claims are barred, in whole or in part, because they violate Immunex' rights under the Due Process and Ex Post Facto clauses of the United States Constitution, as well as the Montana State Constitution, insofar, among other things, as the State seeks to impose liability under vague or nonexistent standards or retroactively for conduct that was not actionable at the time it occurred.
- D. The State's claims are barred, in whole or in part, because Immunex did not make any false statements to the State or its citizens. Immunex had no reasonable grounds to believe, and did not believe, that any statement was false or misleading or capable of being false or misleading.
- E. The communications and conduct of Immunex and others are protected by the First Amendment, Montana State Constitution, and common law privileges, and it would violate those protections to construe the AWP practice and term of art as fraudulent.
- F. The State's claims are barred, in whole or in part, by the government contractor and similar defenses because the reimbursement system, including the use of AWP in excess of actual average prices, was designed and approved by the United States Government to serve its purposes.
- G. Immunex relied on the policies and practices of the federal and Montana state governments, and the State is estopped or otherwise barred from seeking to impose liability for such reliance.

- H. The State's approach to AWP would discourage legitimate price competition and is inconsistent with and preempted by the Sherman Act.
 - I. The claims are barred, in whole or in part, because, *inter alia*, in directly or indirectly adopting "AWP" outside of its government reimbursement and industry context the State or those on behalf of whom it is acting acted recklessly and assumed all risks that it or its representatives might not understand it properly, because it is bound by the federal government's knowledge and purposes, and because it consented to and ratified use of AWP.
- 4. The State's state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, regulations promulgated under those acts, and by the dormant Commerce Clause of the United States Constitution.
 - 5. The State's claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or expressive conduct by Immunex, healthcare providers, or others directed at judicial, legislative, or administrative bodies of government.
 - 6. The State's claims are barred, in whole or in part, by the applicable statutes of limitations and repose.
 - 7. The State's claims are barred, in whole or in part, by the doctrines of laches, estoppel, and waiver.

8. The State has no standing or capacity to bring, and is not the real party in interest with respect to, some or all of the claims raised in this suit, including but not limited, to the State's asserted status in *parens patriae* to recover Medicaid or Medicare expenditures or to seek injunctive relief.
9. Immunex denies that the State has met the statutory and case law requirements of the Montana Consumer Protection Act. However, if such claims are found to exist, Immunex pleads all available defenses under the Act, including standing, lack of direct purchaser, federal preemption, and lack of consumer status or involvement.
10. The State's claims for declaratory or equitable relief are barred because the State has an adequate remedy at law, because the claims were rendered moot by the passage of the 2003 Medicare reform legislation, and due to the doctrine of *in pari delicto* or unclean hands.
11. The State's claims are barred, in whole or part, with respect to any alleged overcharge or supracompetitive price because third party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums or in other ways; because such supracompetitive price, if any, was absorbed, in whole or part, by a person or entity that purchased the medicine directly, or by an intermediate indirect purchaser, and was not passed through; or because purchasers who paid directly or indirectly on the basis of an allegedly excessive AWP would have paid more with respect to this or other elements of health care pricing in the absence of AWP.

12. To the extent the State obtains or has obtained recovery or has benefited from another entity's recovery in this or any other case or through any other method predicated on the same factual allegations, the State is barred from seeking recovery against Immunex based on the SAC.
13. The State's claims are barred, in whole or in part, to the extent it has released, settled, entered into an accord and satisfaction, or otherwise compromised its claims.
14. The State's claims are barred, in whole or in part, due to its failure to join indispensable parties.
15. The State's claims are barred, in whole or in part, because any injuries sustained by the State were the result of intervening or superceding conduct of third parties or of the State or its agents or representatives.
16. The State's claims are barred, in whole or in part, because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.
17. The State's claims are barred, in whole or in part, because it failed to mitigate its damages, and its failure to mitigate damages should proportionately reduce the recovery and the allocation of any fault, if any exists, attributable to Immunex.
18. The State's claims are barred, in whole or in part, because it would be unjustly enriched if allowed to recover any portion of the damages alleged in the SAC.
19. Immunex is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by the

State or those on whose behalf it acts with respect to the same alleged injuries.

20. Any damages recovered by the State from Immunex must be limited by any applicable statutory ceilings on recoverable damages.
21. Any punitive damages would be excessive, penal in nature, and subject Immunex to multiple and retroactive liability and deny Immunex constitutionally adequate standards, instructions, and procedures.
22. The State's claims for punitive damages are barred by the Federal and Montana State Constitution, common law, and public policies.
23. Maintenance of this action would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch.
24. Maintenance of this action in one proceeding against many defendants and absent those on whose behalf, directly or indirectly, the State pursues this action would violate Immunex' rights under the federal and state constitutions by denying Immunex procedural and substantive safeguards.
25. The State's claim for punitive and other damages against Immunex cannot be sustained because any award without the apportionment of the award separately and severally between or among the defendants and other alleged responsible parties, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Immunex' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Montana State Constitution, common law, and public policies.

26. Immunex maintained policies regarding samples, grants, and other issues that prohibited unlawful or questionable practices. Immunex regularly instructed relevant employees as to such policies. To the extent that Immunex had knowledge of conduct that could be viewed as improper, Immunex took prompt and reasonable steps to correct and halt such conduct, including disciplinary action against employees.
27. Immunex adopts by reference any additional applicable defense pled by any other defendant not otherwise pled in this answer. Immunex hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense. Immunex also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part of it, is governed by the substantive law of the State of Montana.

PRAYER FOR RELIEF

WHEREFORE, Defendant Immunex Corporation requests the following relief:

- A. Dismissal of the State's claims with prejudice;
- B. An award of attorneys' fees and costs; and
- C. Such other legal and equitable relief as the Court deems proper.

DATED this 12th day of July, 2004.

/s/ Gary M. Ronan

Thomas J. Sartory, BBO #442500

Gary M. Ronan, BBO #653899

GOULSTON & STORRS, P.C.

400 Atlantic Avenue

Boston, MA 02110-3333

(617) 482-1776

tsartory@goulstonstorrs.com

gronan@goulstonstorrs.com

David J. Burman, WSB #10611

Kathleen M. O'Sullivan, WSB #27850

Zoe Philippides, WSB #30532

Charles C. Sipos, WSB #32825

PERKINS COIE LLP

1201 Third Avenue, Suite 4800

Seattle, WA 98101-3099

(206) 359-8000

dburman@perkinscoie.com

kosullivan@perkinscoie.com

zphilippides@perkinscoie.com

csipos@perkinscoie.com

Attorneys for Defendant

IMMUNEX CORPORATION